Ex 18 - MCK-AGMS-006-0001048-1071

Plaintiffs' Opposition to Defendants' Motion for Summary Judgment on Proximate Causation Grounds

SETTLEMENT AND RELEASE AGREEMENT
AND
ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Settlement and Release Agreement and Administrative Memorandum of Agreement ("Agreement") is entered into on this 2nd day of May 2008, by and between the United States Department of Justice, Drug Enforcement Administration (hereinafter "DEA") and McKesson Corporation including facilities doing business as McKesson Pharmaceutical and McKesson Drug Company (hereinafter "McKesson") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to McKesson and all McKesson DEA registered facilities as identified in Appendix A.

BACKGROUND

WHEREAS, on August 4, 2006, DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued an Order to Show Cause ("Order #1") to McKesson, with respect to its Lakeland distribution center located at 1515 West Bella Vista Street, Lakeland, Florida 33805 (the "Lakeland Facility"); and

WHEREAS, Order #1 alleged, among other things, that McKesson failed to maintain effective controls at the Lakeland Facility against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, after service of Order #1 on McKesson, representatives of DEA and McKesson entered into discussions on how best to resolve the issues raised in the Order; and

WHEREAS, on November 1, 2007, DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued a second Order to Show Cause to McKesson ("Order #2," and "Orders" when jointly referring to Order #1 and Order #2), with respect to its Landover distribution center located at 7721 Polk Street, Landover, Maryland, 20785 (the "Landover Facility"); and

WHEREAS, Order #2 alleged, among other things, that McKesson failed to maintain effective controls at the Landover Facility against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, DEA alleges that McKesson failed to maintain effective controls at its Conroe, Texas distribution center (the "Conroe Facility") against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, DEA alleges that McKesson failed to maintain effective controls at its Denver, Colorado distribution center (the "Denver Facility") against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, DEA alleges that McKesson has failed to report suspicious orders of controlled substances and to report thefts or significant losses of controlled substances as more fully set forth in Appendix B, Paragraph 8 as required by 21 C.F.R. 1301.74(b); and

WHEREAS, McKesson is registered with DEA at 39 facilities as distributors of Schedule II-V controlled substances under the provisions of the Comprehensive Drug Abuse Prevention Control Act of 1970, Title 21 U.S.C. § 801 et seq., ("CSA" or "the Act"); and

WHEREAS, McKesson denies the allegations set forth in the Orders and as otherwise summarized above and also denies any allegations of improper conduct including but not limited to allegations that it failed to maintain effective controls against diversion or failed to file suspicious order reports; and

WHEREAS, the Parties believe that the continued cooperation between the Parties to reduce the potential for diversion is in the public interest, including but not limited to sharing of information related to the distribution of controlled substances; and

WHEREAS, the Parties believe that a settlement in this matter is in the public interest and desire to settle and resolve all outstanding claims and/or issues with respect to the Orders and allegations.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, and intending to be legally bound hereby, the Parties hereto agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, the Parties agree to resolve this matter according to the Terms and Conditions below.

2. No Admission or Concession. This Agreement is neither an admission by McKesson of liability or of any allegations made by DEA in the Orders and investigations, nor a concession by DEA that its allegations in the Orders and investigations are not well-founded.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following:

(i) the conduct alleged in the Orders;

(ii) the alleged failure of McKesson to maintain adequate controls against the diversion of controlled substances, on or prior to December 31, 2007, at all distribution facilities operated, owned, or controlled by it;

(iii) the conduct described in Appendix B, Paragraph 8 to this Agreement; and

(iv) the alleged failure of McKesson to detect and report suspicious orders of the controlled substances as required by 21 C.F.R. § 1301.74(b) on or before December 31, 2007.

4. DEA Headquarters. For purposes of this Agreement, the DEA Representative shall be the Chief, Pharmaceutical Investigations Section, Operations Division, DEA Headquarters.

5. McKesson Representative. For purposes of this Agreement, the McKesson Representative shall be the Senior Vice President, Distribution Operations or the Vice President, Regulatory Affairs.

II. Terms and Conditions

1. Obligations of McKesson.

(a) McKesson agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders that exceed established thresholds and criteria will be reviewed by a McKesson employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should be not filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels. Orders identified as suspicious will be reported to the DEA as discussed in subsection II.1(c). This compliance program shall apply to all current and future McKesson distribution centers registered with the DEA in the United States and its territories and possessions. McKesson acknowledges and agrees that the obligations undertaken in this subparagraph do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.

(b) Within five (5) business days following the date of each controlled substance transaction, McKesson shall provide DEA Headquarters with a report of all controlled substance transactions through Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. This information will be based on raw sales data and will not be reconciled in the manner that Automation of Reports and Consolidated Orders System (ARCOS) data is reconciled, nor does this requirement supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the data provided in this report shall be a true and correct copy of the raw transaction data at the time that the data is transmitted to the DEA and thus does not contain any adjustments or corrections that would normally be part of McKesson's reconciliation of its business records. The Parties agree that the report does not

otherwise constitute the basis for McKesson's compliance with recordkeeping and reporting requirements under the CSA or applicable DEA regulations. The Parties agree that such report is not required under the CSA or DEA regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5). McKesson shall begin transmitting this information no later than 120 days after the Parties have mutually agreed upon a format. The obligations contained in this paragraph shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination of the obligations contained in this paragraph.

(c) McKesson shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, McKesson shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA agrees to notify all of the DEA Field Offices within 30 days of the Effective Date of this Agreement that McKesson will no longer be required to provide suspicious order reports or any other type of reports regarding excessive purchases of controlled substances to the DEA Field Offices and that this Agreement shall supersede any DEA regulatory requirements to report suspicious orders to DEA. The obligations contained in this paragraph shall be and remain in full force and effect from the Effective Date of this Agreement, and thereafter shall remain in full force and effect unless terminated and revoked by DEA with thirty (30) days written notice.

(d) McKesson agrees to a temporary suspension of its authority to distribute drugs containing the drug codes for Schedule III hydrocodone combination products and alprazolam, that is, DEA drug codes 9805, 9806 and 2882 with respect to the DEA registrations for its Lakeland Facility and its Conroe Facility, except for sales to the accounts as listed in Appendix C. The temporary suspension shall terminate in accordance with subsection II.2(g) unless sooner terminated by the Parties in writing pursuant to the terms of this Agreement.

(e) McKesson agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to McKesson's obligations to detect and report suspicious orders in accordance with 21 C.F.R. §1301.74(b).

(f) McKesson agrees that within 120 days of the Effective Date of this Agreement it will review distributions of hydrocodone and alprazolam for the 24-month period immediately preceding the execution of this Agreement and identify any current customer whose purchases of hydrocodone and alprazolam exceeded the thresholds established in its compliance program. McKesson shall conduct an investigation and take appropriate action as required by this Agreement, DEA regulations and other procedures established under McKesson's compliance program including its Controlled Substance Monitoring Program (CSMP).

(g) McKesson's policy and procedure is to cooperate with the government in any investigation. McKesson agrees to reasonably cooperate with DEA, the United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any

pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by the DEA or other law enforcement authorities. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party.

(h) McKesson agrees to pay civil penalties to the United States of America under 21 U.S.C. § 842(c) for violations of 21 U.S.C. § 842(a)(5) in the amount of $13,250,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances and for failing to report thefts or significant losses of controlled substances. Payment of said civil penalties shall be made by McKesson in the amounts indicated and as directed by the United States Attorneys' Offices set forth in Appendix B, Paragraph 13. McKesson agrees to execute the Settlement Agreement at Appendix B simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said civil penalties within 30 days of the Effective Date of this Agreement.

(i) Any material breach by any McKesson facility of subsections II.1(a)-(h) of this Agreement by McKesson after the Effective Date of this Agreement may be a basis upon which DEA can issue an Order to Show Cause seeking the revocation of McKesson's DEA certificate(s) of registration for that facility.

2. Obligations of DEA.

(a) At McKesson's request, DEA shall continue to provide diversion prevention and awareness training, as practicable, to retail pharmacy industry members at McKesson trade shows and through written materials. The frequency and content of such training shall be at DEA's sole discretion.

(b) DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as required under 21 C.F.R. §1301.74(b) and described in subsection II.1(c) of this Agreement. DEA agrees that this procedure is consistent with DEA regulatory requirements and hereby waives the regulatory requirement to report suspicious orders of controlled substances to the DEA Field Division Offices.

(c) DEA agrees and acknowledges that neither the CSA, DEA regulations, nor the terms of this Agreement establish a requirement that reporting of a suspicious order means that a customer be designated as a suspicious customer that would de facto require the suspension of all orders or sales of other controlled substances to this customer.

(d) DEA agrees that any request made by DEA or any of its employees that McKesson continue to sell controlled substances to customers for an order that McKesson has determined to be suspicious shall be made in writing to the designated McKesson Representative.

(e) Within 150 days of the Effective Date of this Agreement, but not earlier than 90 days after the Effective Date of this Agreement, DEA shall conduct reviews of the functionality of McKesson's diversion compliance program ("Compliance Reviews") at up to eight distribution centers of McKesson, consisting of the Lakeland Facility; the Landover Facility; the Conroe Facility; and five other McKesson distribution centers selected by DEA. DEA shall also review the investigatory files maintained by McKesson of the customers serviced by the distribution centers subject to the Compliance Reviews. DEA shall notify McKesson no less than 48 hours prior to commencing a Compliance Review at a distribution center. DEA shall issue a Notice of Inspection to McKesson upon commencement of a Compliance Review. During the course of a Compliance Review, if requested, McKesson shall provide DEA with information related to the sales of controlled substances, non-controlled drugs, and listed chemicals from Effective Date of Agreement, to the date of the Compliance Review by the particular distribution center being reviewed. At the conclusion of each Compliance Review, DEA shall conduct an exit interview with an appropriate McKesson representative to provide DEA's preliminary conclusions regarding the Compliance Review.

(f) The Compliance Reviews will be deemed satisfactory unless DEA determines that one or more of the facilities being inspected has (i) failed to maintain effective controls against diversion regarding the distribution of any controlled substance; (ii) failed to detect and report to DEA suspicious orders of controlled substances; or (iii) failed to meaningfully investigate new or existing customers regarding the customer's legitimate need to order or purchase controlled substances. The Compliance Reviews shall be deemed "not satisfactory" if DEA provides written notice with specificity to McKesson on or before 165 days from the Effective Date of Agreement, stating that McKesson failed to meet any of the requirements in either subsections II.2(f)(i), (ii), or (iii) of this Agreement. DEA shall not find a Compliance Review "not satisfactory" unless the failure(s) are sufficient to provide DEA with a factual and legal basis for issuing an Order to Show Cause under 21 U.S.C. § 824(a) against one or more of the inspected facilities. In the event that DEA provides such written notice of a Compliance Review Failure(s), DEA shall meet and confer with McKesson within 48 hours regarding such a finding. DEA shall consider remedial measures that McKesson has instituted in determining whether the Compliance Reviews are satisfactory. A finding of "satisfactory" does not otherwise express DEA's approval of the compliance program implemented at any particular distribution center.

(g) Upon the completion of the Compliance Reviews and within 180 days of the Effective Date of this Agreement, DEA will restore the drug codes 9805, 9806 and 2882 to the DEA registrations for the Lakeland and Conroe Facilities. In the event that McKesson has not satisfied DEA in regard to the Compliance Reviews within 180 days of the Effective Date of this Agreement and DEA issues a Show Cause against either of the Lakeland or Conroe Facilities, McKesson agrees to a new period of suspension of the drugs codes at such facility until the matter is resolved by mutual agreement of the Parties or a final decision by the DEA Deputy Administrator. Notwithstanding, nothing in this Agreement shall prevent the Parties from agreeing to an extension or shortening of the suspension period for these drugs codes at the Lakeland and Conroe Facilities at any time during the course of this Agreement. DEA shall not be prevented from taking any action that would otherwise be available to the agency to pursue a new period of suspension of the drug codes at these facilities.

(h) DEA shall execute this Agreement only upon obtaining a fully executed copy of the Settlement Agreement at Appendix B.

(i) In the event that DEA discovers information that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement; all actions taken by McKesson pursuant to this Agreement; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility and at other McKesson facilities.

(j) DEA represents that it has reviewed its records for investigations or inspections, initiated or conducted prior to December 31, 2007, which may allege that McKesson failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA further represents that it has reviewed reports and records submitted by McKesson to DEA on or before December 31, 2007 for indications that McKesson may have failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA has not referred and agrees to not refer any conduct (other than conduct in Appendix B, Paragraph 8) occurring before December 31, 2007, for civil penalty proceedings under to 21 U.S.C. § 842(a)(5) that would be based on the Covered Conduct, to any other agency within the Department of Justice.

3. Joint Obligations of the Parties. McKesson and DEA agree that upon the execution of this Agreement, DEA and McKesson shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings against the Lakeland Facility and Landover Facility.

4. Release by DEA. (i) In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:

(i) Release McKesson from any administrative claims within DEA's enforcement authority for the conduct alleged in the Orders; and

(ii) Refrain from filing any administrative claims against McKesson within DEA's enforcement authority under21 U.S.C. §§ 823, 824 and 842, based on the Covered Conduct, only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of December 31, 2007, and the review of the reports and records McKesson submitted to DEA prior to December 31, 2007.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct in any other administrative proceedings. Further, nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof ("law enforcement agency"), from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any law enforcement

agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other law enforcement agency and will represent that McKesson's compliance with this Agreement adequately addressed the administrative and civil allegations raised by DEA as defined in the Covered Conduct. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

5. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:

(a) Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

(b) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct subject to Paragraph II.4 of this Agreement; or

(c) Any liability based upon such obligations as are created by this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties.

McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) five (5) business days after the date of signing by the last signatory (the "Effective Date"). The government agrees to notify McKesson immediately when the final signatory has executed this Agreement.

6. Disclosure. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction. However, the Parties agree to provide each other with advance notice the day before or as soon as possible once a decision has been made to issue any public statement or press release related to this Agreement. The Parties shall provide copies of any press release no later than two hours before issuing the press release. This paragraph does not apply to any press release or public statement issued by the Department of Justice or any United States Attorney's Office. This paragraph shall remain in effect for sixty (60) days, commencing with the Effective Date of the Agreement.

7. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

8. Authorizations. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

9. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties under subsections II(2)(a-d) of this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the McKesson distribution facility(s) at issue is located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Settlement and Release Agreement as of the date written above.

MCKESSON CORPORATION

By: _____
John H. Hammergren
President
McKesson Corporation

Dated: April 28, 2008

By: _____
Donald G. Walker
Senior Vice President
McKesson Corporation

Dated: April 30, 2008

THE UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

By: _____
Michele M. Leonhart
Acting Administrator
Drug Enforcement Administration

Dated: May 2, 2008

By: _____
Wendy H. Goggin
Chief Counsel
Drug Enforcement Administration

Dated: May 1, 2008

Appendix A

McKesson Distribution Center DEA Registered Facilities

Location	DEA Registration #
Carol Stream, IL	RM0220599
Methuen, MA	PM0020850
West Seneca, NY	PM0003094
Everett, WA	PM0150538
Anchorage, AK	RM0227430
Aurora, CO	PM0018425
Livonia, MI	PM0030849
Honolulu, HI	PM0001014
Santa Fe Springs, CA	PF0000012
Duluth, GA	PR0040357
Memphis, TN	PM0001951
Washington Ct. House, OH	RM0220688
Oklahoma City, OK	RM0138328
La Vista, NE	PM0038693
Tolleson, AZ	PM0021131
Wilsonville, OR	PM0022929
La Crosse, WI	RM0220537
Delran, NJ	RM0173055
Salt Lake City, UT	PM0023046
West Sacramento, CA	PM0021535
O'Fallon, MO	PM0037374
Memphis, TN	RM0207286
Lakeland, FL	PM0000771
New Castle, PA	RM0258601
Landover, MD	PD0029567
Aberdeen, SD	RM0335869
Conroe, TX	RM0328408
McCalla, AL	RM0336950
Little Canada, MN	PM0036334
Cape Girardeau, MO	RM0337534
Rocky Hill, CT	PR0104593
Aurora, CO	RM0354958

Appendix B

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into this 30th day of April, 2008, by and between the United States Department of Justice, through the United States Attorney's Offices for the Districts of Maryland, Middle Florida, Southern Texas, Colorado, Utah and Eastern California ("United States") and McKesson Corporation including facilities doing business as McKesson Pharmaceuticals and McKesson Drug Company, ("McKesson") and collectively referred to as "the Parties."

RECITALS

1. McKesson is a Delaware corporation and is headquartered in San Francisco, California. Among other things, McKesson is in the business of distributing branded and generic prescription drugs, as well as over-the-counter medications, to retail pharmacies throughout the United States. In furtherance of this business objective, McKesson operates numerous distribution facilities in the United States, including six facilities more fully described in Attachment A to this Agreement ("the Six Facilities").

2. As more fully described in Attachment A, McKesson holds Certificates of Registration issued by the Drug Enforcement Administration ("DEA") authorizing it to distribute controlled substances from these facilities including the Six Facilities.

3. McKesson is required to operate the Six Facilities in accordance with the statutory and regulatory provisions of the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("the CSA").

4. Each of the Six Facilities supplies prescription medications, including controlled substances, to retail pharmacies and other health care providers within the respective

